

COVID-19 Therapeutics Information Brief

June 1, 2022

Changes to the document from the previous version are highlighted in yellow.

The next Therapeutics Information Brief will be June 15, 2022.

IMPORTANT/NEW COVID-19 Therapeutics Information

- CDC Health Advisory Issued for COVID-19 Rebound After Paxlovid Treatment
- Bamlanivimab Self-Life Extension - May 20, 2022
- Sotrovimab Shelf-Life Extension - Reminder
- Paxlovid Shelf Life Extension - Reminder
- Clinical Resources for Paxlovid
- Renal Packaging for Paxlovid 150mg; 100mg Dose Pack for Patients with low eGFR
- Allocation Cadence Changes for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals
- Allocations Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals
- COVID-19 Therapeutics Information Resources

CDC Health Advisory Issued for COVID-19 Rebound After Paxlovid Treatment

The Centers for Disease Control and Prevention (CDC) issued a [Health Alert Network \(HAN\) Health Advisory](#) to update healthcare providers, public health departments, and the public on the potential for recurrence of COVID-19 or "COVID-19 rebound."

- Paxlovid continues to be recommended for early-stage treatment of mild to moderate COVID-19 among persons at high risk for progression to severe disease.
 - Paxlovid treatment helps prevent hospitalization and death due to COVID-19. COVID-19 rebound has been reported to occur between 2 and 8 days after initial recovery and is characterized by a recurrence of COVID-19 symptoms or a new positive viral test after having tested negative.
 - A brief return of symptoms may be part of the natural history of SARS-CoV-2 (the virus that causes COVID19) infection in some persons, independent of treatment with Paxlovid and regardless of vaccination status.
 - Limited information currently available from case reports suggests that persons treated with Paxlovid who experience COVID-19 rebound have had mild illness; there are no reports of severe disease.
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Bamlanivimab Self-Life Extension - May 20, 2022

May 20, 2022, the FDA authorized extension to the shelf-life from 12 months to 18 months for specific lots of the refrigerated Eli Lilly monoclonal antibody, bebtelovimab.

- Some batches may be stored for an additional 6 months from the labeled date of expiry (see Table) and, as required by the emergency use authorization for bebtelovimab, unopened vials of bebtelovimab injection, 175 mg/2 mL, must be stored under refrigerated temperature at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.
- FDA granted this extension following a thorough review of data submitted by Eli Lilly. This extension applies to all unopened vials of bebtelovimab that have been held in accordance with storage conditions detailed in the authorized [Fact Sheet for Health Care Providers](#) and the [Letter of Authorization for Emergency Use Authorization \(EUA\)](#) 111 for bebtelovimab.

**Extended Expiry Dating for Bebtelovimab
Authorized under EUA 111**

Batch Number	Labeled Expiry Date	Extended Expiry Date
D476887	2022-07-11	2023-01-11
D476886	2022-07-13	2023-01-13
D487999	2022-07-13	2023-01-13
D480382	2022-10-27	2023-04-27
D488000	2022-10-27	2023-04-27
D492098	2023-02-16	2023-08-16
D494710	2023-02-16	2023-08-16
D493128	2023-02-17	2023-08-17

Sotrovimab Shelf-Life Extension - Reminder

On September 21, 2021, FDA and ASPR authorized an extension to the shelf-life from 12 months to 18 months for all lots of the refrigerated GSK monoclonal antibody, sotrovimab. Due to the high frequency of the Omicron BA.2 variant, sotrovimab is not currently authorized in any U.S. region. *Therefore, this drug may not be administered for treatment of COVID-19 under the Emergency Use Authorization until further notice by the Agency.*

Retained product must be appropriately held in accordance with storage conditions detailed in the authorized [Fact Sheet for Health Care Providers](#) and the [Letter of Authorization for Emergency Use Authorization \(EUA\)](#) 100.

Evaluation of future extension of shelf-life for sotrovimab is ongoing. FDA will continue to evaluate the available data and provide updated information as soon as possible. All sotrovimab vials may continue to be retained regardless of the current labeled expiry date or previously provided extension dates, unless otherwise notified by the Agency.

**Extended Expiry Dating for Sotrovimab
Authorized under EUA 100**

Batch Number	Labeled Expiry Date	Extended Expiry Date
658W	2022-02	2022-08
XV6W	2022-04	2022-10
Y74D	2022-04	2022-10
JP9Y	2022-04	2022-10
287F	2022-04	2022-10
287X	2022-05	2022-11
432U	2022-05	2022-11
433C	2022-05	2022-11

Paxlovid Shelf Life Extension - Reminder

The FDA has authorized the following extended expiry dates for certain lots of Paxlovid.

Drug Name	Lot#	Extended Expiry Date
Paxlovid	FL4516, FL4517, FR7229	The initial 3 lots were extended from 7/31 to 10/31/22.
	FR9088	4th lot was extended from 8/31 to 11/30/22

Clinical Resources for Paxlovid - NEW!

Paxlovid is now widely available. Although COVID-19 hospitalizations have decreased, some high-risk patients are becoming ill enough to require hospital admission. Early treatment with Paxlovid and other available authorized or approved therapeutics could make a difference. FDA has released a new [Paxlovid Patient Eligibility Screening Checklist for Prescribers](#). This checklist is intended as an aid to support clinical decision making for prescribers. However, use of this checklist is not required to prescribe Paxlovid under the EUA.

- [Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers](#)
- [University of Liverpool COVID-19 Drug Interactions](#)
- [Pfizer Drug Interaction Checker](#)
- [NIH COVID-19 Treatment Guidelines -Ritonavir-Boosted Nirmatrelvir\(Paxlovid\)](#)
- [CDC/IDSA COVID-19 Clinician Call: All About Paxlovid; Plus Variants Update](#)

Renal Packaging for Paxlovid 150mg; 100mg Dose Pack for Patients with low eGFR

FDA updated the Paxlovid EUA to authorize an additional dose pack presentation of Paxlovid with appropriate dosing for patients within the scope of this authorization with **moderate** renal impairment.

- Each 150 mg; 100 mg Dose Pack includes 5 daily blister cards
- Each blister card contains a morning and evening dose
- Each dose consisting of 150mg nirmatrelvir (one oval, pink 150 mg tablet) and 100mg ritonavir (one white or white to off-white film-coated 100mg tablet uniquely identified by the color, shape and debossing)

The HCP and Pharmacist Instructions are available at: <https://www.covid19oralrx-hcp.com/resources>



Standard Dose

300 mg nirmatrelvir; 100 mg ritonavir: Each carton contains 30 tablets divided in 5 daily dose blister cards. Each blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

Renal Dose

150 mg nirmatrelvir; 100 mg ritonavir: Each carton contains 20 tablets divided in 5 daily dose blister cards. Each blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

If the renal packaging of Paxlovid is not available, healthcare providers may use the standard dose pack of Paxlovid and adjust the dosing per the [Dear HCP Letter](#) guidance issued by the FDA for patients with renal impairment.

Allocations Cadence Changes for Monoclonal Antibodies, PReP Treatment and Antivirals

Antivirals will shift to a weekly allocation cycle. This will align with the weekly allocation cadence for monoclonal antibodies (Bebtelovimab and sotrovimab) and the pre-exposure prophylaxis treatment (Evusheld). The ordering cadence will be as follows:

- Allocation Survey Sent - Monday
- Allocation Survey Due Back to IDPH - Tuesday at 4:00pm
- Allocation Ordered in Federal System - Thursday
- Allocation Amount Notification from IDPH to healthcare providers - Thursday

Allocations Threshold Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals

Iowa Statewide Allocations Threshold Remaining for the week Monday, May 30, 2022 - Sunday June 5, 2022				
mAbs	Oral AVs			PrEP
Bebtelovimab	Molnupiravir (Lagevrio)	Paxlovid	Renal Paxlovid	EVUSHELD
165 courses	312 courses	880 courses	80 courses	1824 doses (monthly allocation)

- The minimum order quantity for Molupiravir is 24 courses.
- **Allocations will not include sotrovimab, bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV).**

- IDPH encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.
 - The Department of Health and Human Services has released a [COVID-19 Therapeutics locator](#).
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COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center** - To reach the IDPH COVID-19 Therapeutics Call Center, call 515-281-7317.
- **COVID-19 Therapeutics Email** - Therapeutic questions from healthcare providers can be emailed to: C19Therapeutics@idph.iowa.gov
 - NOTE: **The COVID-19 Therapeutics Call Center and Email are intended for healthcare providers only.**
- [COVID-19 Therapeutics Table](#)- IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.
- [Outpatient Therapeutics Decision Aid](#)
- [Side-by-Side Overview Outpatient Therapeutics](#)
- [Product Expiration Date Extensions](#)
- [NIH COVID-19 Treatment Guidelines](#), last updated: April 8, 2022